DOSING FLOW CHART

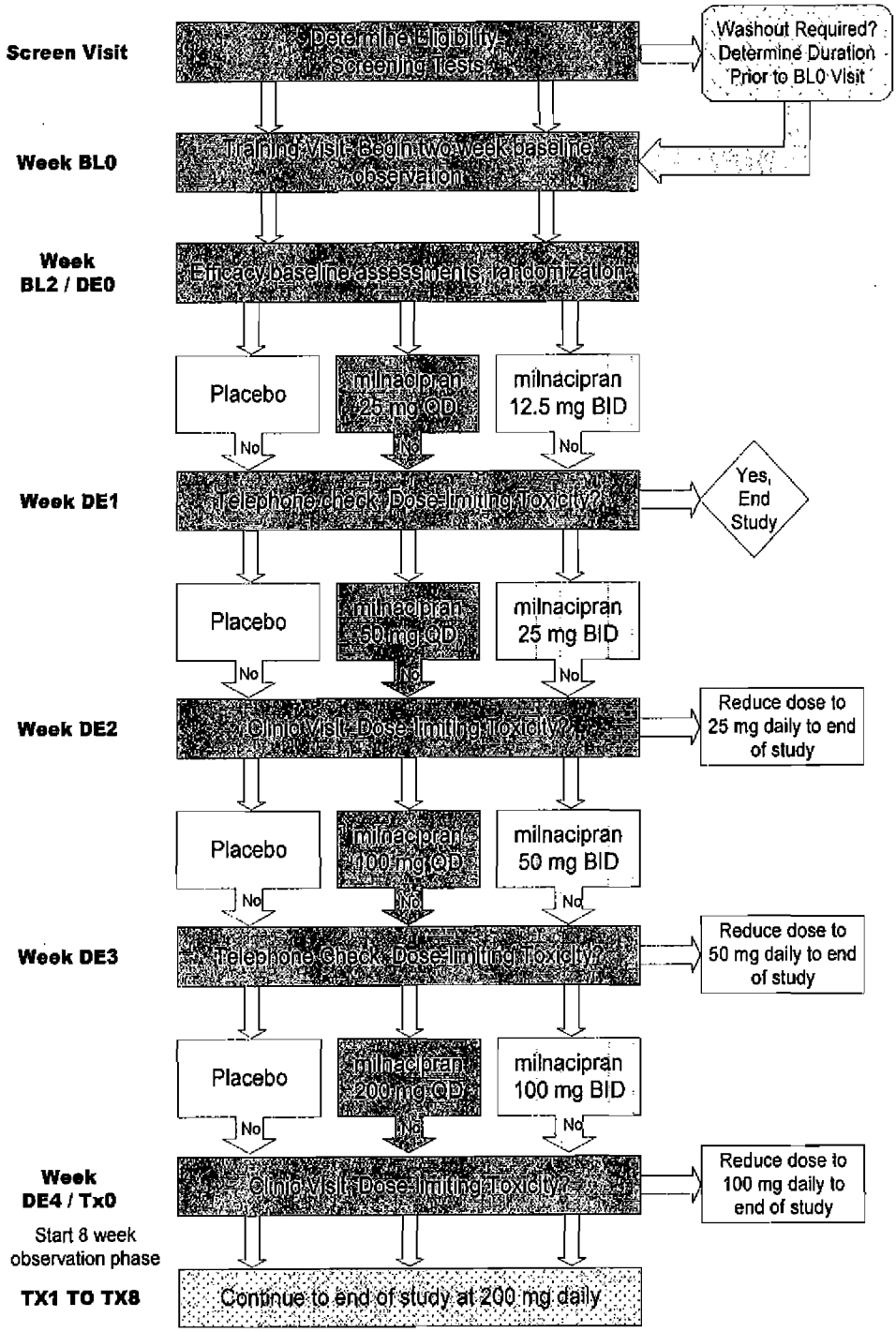
Screen Visit
Determine Eligibility: Screening Tests
Washout Required? Determine Duration Prior to BL0 Visit
Week BL0
Training Visit: Begin two week baseline observation
Week BL2 / DE0
Efficacy baseline assessments, randomization
Placebo
milnacipran 25 mg QD
milnacipran 12.5 mg BID
No
Week DE1
Telephone check: Dose-limiting toxicity?
Yes, End Study
Placebo
milnacipran 50 mg QD
milnacipran 25 mg BID
Week DE2
Clinic visit: Dose-limiting toxicity?
Reduce dose to 25 mg daily to end of study
Placebo
milnacipran 100 mg QD
milnacipran 50 mg BID
Week DE3
Telephone check: Dose-limiting toxicity?
Reduce dose to 50 mg daily to end of study
Placebo
milnacipran 200 mg QD
milnacipran 100 mg BID
Week DE4 / Tx0
Clinic visit: Dose-limiting toxicity?
Reduce dose to 100 mg daily to end of study
Start 8 week observation phase
TX1 TO TX8
Continue to end of study at 200 mg daily

Figure 1
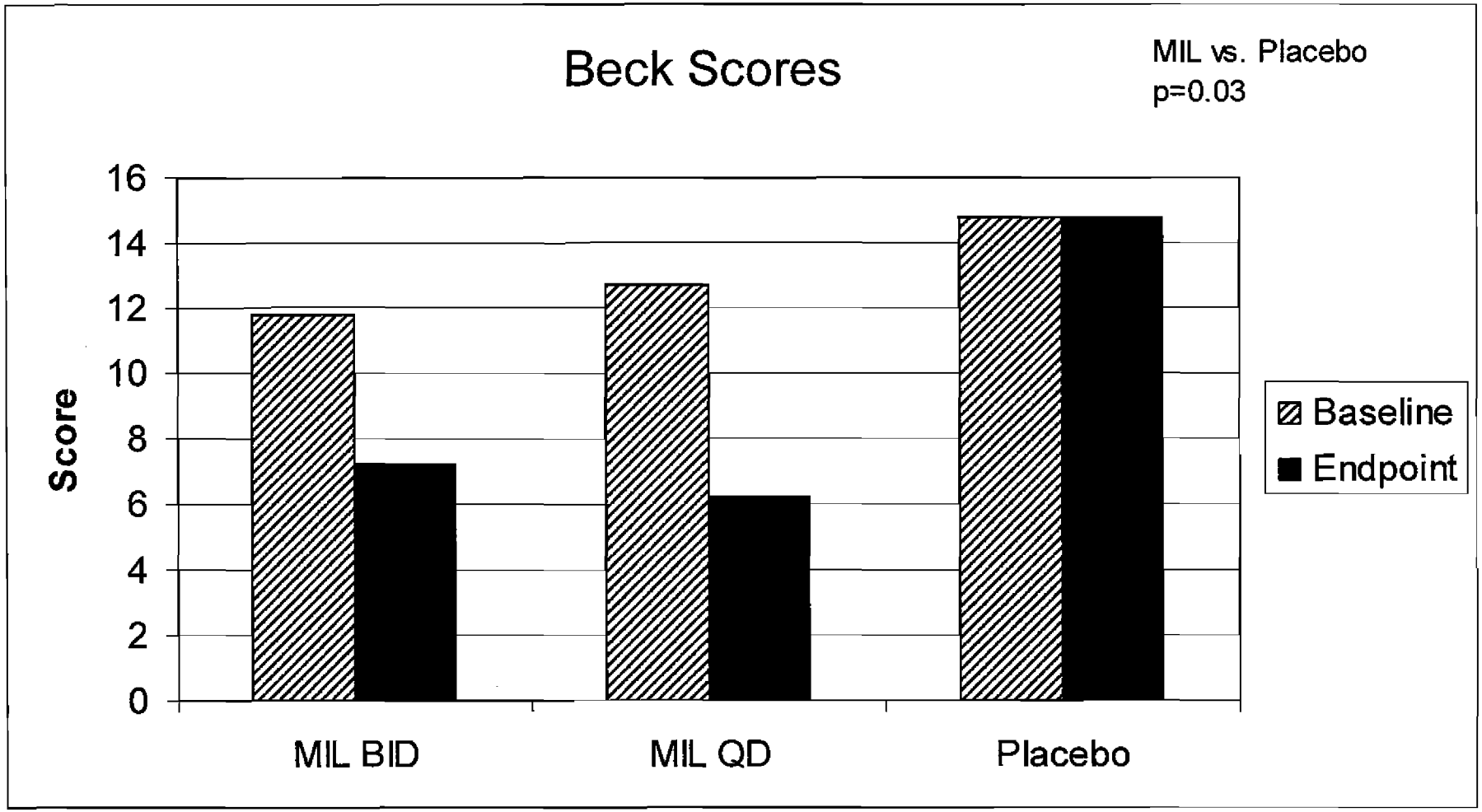
Figure 3 Beck Scores